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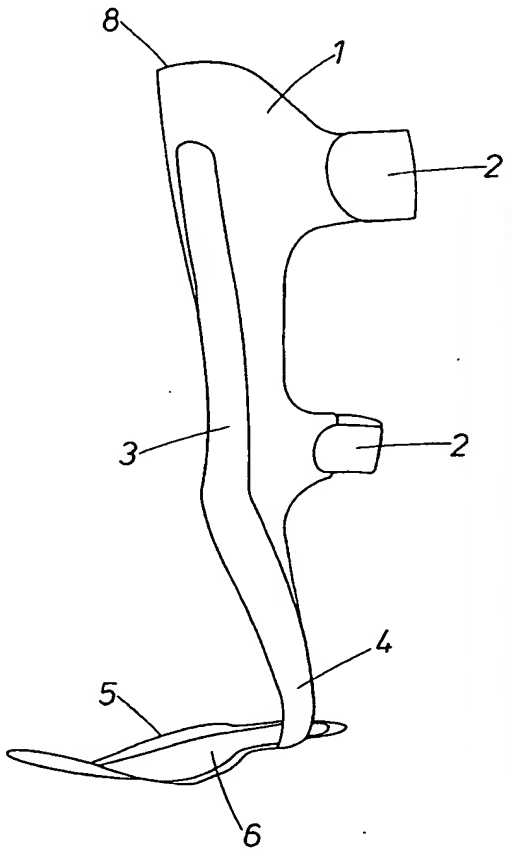
(54) Title: ANKLE–FOOT ORTHOSIS

(57) Abstract

An ankle–foot orthosis made of a carbon fibre reinforced material having low weight is carried on the front of the lower leg, extending over the lateral ankle and preventing plantar flexion. The orthosis may be worn under ordinary clothes and inside shoes and promotes a more natural gait pattern. The ankle–foot orthosis comprises a frame of thin flexible material extending over the front of the lower leg, anterior of the lateral ankle and beneath the sole of the foot and a supporting portion of rigid material extending over a narrow part of the front of the lower leg, anterior of the lateral ankle and beneath a part of the sole of the foot. The orthosis also comprises a fastening means for fastening the orthosis to the leg. In a preferred embodiment the orthosis comprises a substantially inflexible reinforcement element and a tough flexible element, the reinforcement element extending over a narrow part of substantially the whole frame and the flexible part extending over a substantial part of the sole of the foot. The frame is preferably made of thin flexible fibre glass reinforced plastic resin material, said reinforcement element being made of rigid carbon fibre reinforced plastic resin material. Said tough flexible element is preferably made of aramid fibre reinforced plastic resin.



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ANKLE-FOOT ORTHOSIS

FIELD OF THE INVENTION

This invention relates to an ankle-foot orthosis and, more particularly, an ankle-foot orthosis made of a carbon fibre reinforced material having low weight. It is carried on the front of the lower leg, extending over the lateral ankle and preventing plantar flexion. The orthosis may be worn under ordinary clothes and inside shoes and promotes a more natural gait pattern.

BACKGROUND OF THE INVENTION

The prior art ankle-foot orthosis usually comprises a dorsal splint of metal or plastic extending behind the Achilles tendon and merging with a foot plate under the sole. The orthosis is fastened by straps extending from the dorsal splint around the lower leg.

It is disadvantageous that the splint is located behind the foot and Achilles tendon since the movement of the joint is affected unfavorably producing a stiff gait. Also, the Achilles tendon and calf are often swollen and painful to touch, causing unnecessary pain to the patient and preventing a natural gait which causes heavy stresses on joints and muscles of the lower extremities and sometimes even in the back.

Further, the metal dorsal splint makes the orthosis heavy which is, of course, not comfortable when walking.

Still further, the location of the splint requires space inside the shoe and, thus, the patient's normal shoes cannot be used with the prior art orthosis.

Thus, there is a need for an improved ankle-foot orthosis having light weight and promoting a more natural gait as well as enabling use of the patient's normal clothes and shoes.

SUMMARY OF THE INVENTION

The present invention solves the above-mentioned problem by providing an ankle-foot orthosis comprising a frame of thin flexible material extending over the front of the lower leg, anterior of the lateral ankle and beneath the

sole of the foot and a supporting portion of rigid material extending over a narrow part of the front of the lower leg, anterior of the lateral ankle and beneath the part of the sole of the foot. The orthosis also comprises a fastening means for fastening the orthosis to the leg.

It is preferred that the orthosis comprises a substantially inflexible reinforcement element and a tough flexible element, the reinforcement element extending over a narrow part of substantially the whole frame and the flexible part extending over a substantial part of the sole of the foot.

The frame is preferably made of thin flexible fibre glass reinforced plastic resin material, said reinforcement element being made of rigid carbon fibre reinforced plastic resin material. Said flexible element is preferably made of aramid fibre reinforced plastic resin.

It is an advantage of the present invention that the orthosis is thin and light-weight, enabling use of normal clothes and shoes.

It is a further advantage that the supporting portion extends over the front of the leg and anterior of the lateral ankle enabling the orthosis to take the impact when the heel is put down and support the movement in the toe-off stage to obtain a more normal gait. Also, the springing action of the orthosis resembling a recoil effect will assist the patient to move forward and enables the patient to take longer steps.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an ankle-foot orthosis according to the present invention;

Figure 2 is a cutaway top view of a foot plate of the orthosis of the invention, the contour of a foot being outlined in phantom lines;

Figure 3 is a side view of the orthosis placed on the lower leg of a patient; and

Figure 4 is a gait diagram of an analysis of the gait cycle using orthoses in accordance with the prior art and the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An ankle-foot orthosis according to the present invention is shown in Figure 1. An orthosis for the left foot is shown while it should be understood that a mirror image of the orthosis should be used for the right foot. The orthosis comprises a frame 1 of composite material and straps 2 for securing the orthosis to the lower leg. The straps and orthosis are provided with so-called Velcro or hook-and-loop type surfaces providing an easy means of taking on and off the orthosis.

In the frame 1 a reinforcement element 3 is embedded. The reinforcement element extends over a narrow part of the leg portion of the frame on the front of the lower leg. The reinforcement element 3 continues by way of a brace portion 4 to a foot plate 5 in which the reinforcement element again is embedded as a narrow portion. The reinforcement element fans out from the brace portion 4 to the foot plate portion of the reinforcement element to absorb the forces and torques acting in this narrow transition. As is best shown in Figure 2, the foot plate 5 also comprises another embedded element, viz. a tough flexible element 6. The reinforcement element 3 and the tough element 6 together provide the supporting portion of the orthosis.

Except where the reinforcement element is embedded in the frame 1, the frame 1 is flexible. This means that the orthosis can accommodate thick and thin legs by tightening or loosening the straps. Also, the frame 1 may be cut by an ordinary pair of scissors to adjust the height of the orthosis and width of the foot plate 5 as is described more in detail below.

In order for a prefabricated orthosis to be useful, it must fulfill certain requirements. As is mentioned above, it is flexible in certain areas, making the orthosis easy to take off and put on and making it suitable for extremities having different sizes, and furthermore requiring only a few sizes to fit the majority of the population. It must be

rigid in other areas so as to give an adequate stabilization or immobilisation of the ankle joint and of the lower part of the lower extremities, etc. and it should furthermore have a low weight as well as a surface which is well tolerated both on the inside and the outside.

The frame 1 is made from a thin yarn fabric of fibre-glass which is pre-impregnated with an epoxy matrix into a prepreg. An inner and an outer layer is suitable for an ankle-foot orthosis. For certain orthoses a smaller number of layers may be suitable at the edges of the orthosis to make it more flexible. Each finished layer has a thickness of about 0.2 mm.

Between the fibre-glass layers, the two-part reinforcement element 3 is placed. Where the reinforcement element is to be strongest, e.g. at the brace portion 4, it consists of a carbon fibre fabric impregnated with an epoxy matrix into a prepreg. A number of layers as necessary is used to obtain the suitable strength. If single-direction carbon fibre fabric is used, in the upper portion of the reinforcement element (at 3 in Figure 1), the carbon fibres are conveniently arranged longitudinally to provide a great bending resistance but lesser torsion resistance. The directions of the carbon fibres in the various layers of the brace portion 4 are preferably arranged in a crisscross manner as well as longitudinally to obtain the greatest possible bending and torsion resistance. In the foot plate portion of the reinforcement element, the carbon fibres are conveniently arranged in a crisscross manner to provide a great torsion resistance but lesser bending resistance. Also twill-woven carbon fibre fabric may be used. The cured carbon fibre material has a coefficient of elasticity comparable to that of steel. Each finished layer has a thickness of at least about 0.3 mm. The width of the reinforcement element ranges from 25 to 40 mm depending on the size of the orthosis.

The forming of the prepregs is made on a tool shaped in accordance with a model of the wanted extremity part, in this case the lower leg and the foot, of suitable size. The material is cured in an oven in 120°C for 120 minutes. After this, the material may be surface treated, e.g. painted in

any wanted colour, and the padding and the Velcro fasteners may be applied. It is also possible to use a colored epoxy matrix in which case additional painting of the orthosis will not be necessary.

When using the orthosis, the frame 1 expands if the patient has thick legs whereas it can be pulled together by the Velcro strap fasteners if the patient has thin legs. At the same time, the reinforcement element 3 remains almost completely immobile.

Furthermore, the frame of fibre glass reinforcement plastic resin is not very hard and may be cut by an ordinary pair of scissors. Thus, the height of the orthosis may be adjusted by cutting off a portion at the top edge 8 if the patient has relatively short legs. Also, the width of the foot plate 5 may be adjusted by cutting along the edges thereof in order to accommodate the foot plate 5 inside a shoe. The orthosis of the invention is intended for use inside the patient's normal shoes and this is possible since only the brace portion 4 needs some extra space where it is protruding from the shoe, see especially Figure 2. The patient should use ordinary socks with the orthosis. If necessary, an inner sole of the shoe may be removed for better comfort.

As is seen in Figure 2, the foot plate 5 comprises three portions having different strength and flexibility. In the central part and extending longitudinally of the foot plate, the reinforcement element 3 is embedded as mentioned previously. Overlapping and surrounding the reinforcement element 3 on the foot plate 5 is a further element 6 having great toughness and flexibility. The flexible element 6 is made of a number of layers of aramid fibres (such as sold under the trademark Kevlar) preimpregnated with an epoxy matrix into the prepreg. The epoxy matrix is the same in all the different materials of the orthosis. Of course, the various layers have to be formed at the same time. The peripheral portion of the foot plate only comprises the fibre glass reinforced layer constituting the frame 1. This peripheral portion may be cut off completely, if necessary, for the reasons stated above.

It is contemplated that foot plates 5 having varying

degrees of strength and toughness should be produced. The soft version is intended mainly for indoor use by not very active or agile persons, e.g. older people. The soft version is more comfortable to wear and suitable for walking at a slow to normal pace in small steps. It is a fact that even healthy persons have a "shuffling" gait indoors.

The medium soft version is intended for indoor as well as outdoor use by more active persons. This is the normal version which should be able to withstand substantial loads during walking at a fast pace and also standing still for extended periods.

The soft and medium soft versions have a stabilizing effect on the ankle joint and are suitable for the indications mentioned below. The physician prescribes the suitable version for the patient on the basis of the condition, body weight and activity level of the patient.

Also a hard version is contemplated which is intended for use in connection with fractures, ankle injuries or distortion. The stabilization of the hard version approaches immobilization of the ankle joint while the toes are still somewhat mobile. Beside stabilizing dorsal and plantar flexion, even a stabilization of the pronation and supination is obtained. A person having a fracture could replace the conventional plaster cast after say 4-5 weeks by the ankle-foot orthosis according to the invention.

The table below sets forth the number of layers of the various materials of the foot plate in the respective perferred versions.

	Number of layers		
	Fibre glass	Aramid fibre	Carbon fibre
Soft	3	2	2
Medium	3	3	2
Hard	4	4	3

Of course, a person skilled in the art may use other combinations of material layers varying the number of fibre glass layers in the range of 2-4, the number of aramid fibre layers in the range of 2-5, and the number of carbon fibre layers in the range of 1-4.

It should be appreciated that the brace portion 4 is

the same for the various versions, since this portion always should be almost immobile. However, the large size of the orthosis could have additional carbon fibre layers to withstand the weight of larger and heavier persons.

The ball 10 of the foot 11 is also outlined in Figure 2 by dotted lines. As may be seen, the ball of the foot should be located in front of the reinforcement element 3 but supported by the flexible element 6. This enables bending upwards of the toes when walking as is described in further detail below with reference to the gait pattern analysis of Figure 4.

As is shown in Figure 3 the orthosis is carried on the lower leg 9. In Figure 3, the lower leg is outlined together with the skeleton bones in phantom lines. It may be seen that the brace portion 4 runs anterior or in front of the lateral foot joint 7 resulting in a natural gait pattern and other advantages as is outlined below. In Figure 3 the straps 2 are not shown for better clarity.

The orthosis is produced in three sizes in order to fit the majority of the adult population, both male and female (and two sizes for children). The small size of the orthosis takes shoe-sizes up to 38 (U.S. up to 10), medium: shoe-size 38-42 (U.S. 10-11) and large: shoe-size 42-45 (U.S. 11-12).

The soft and medium soft orthosis is suitable for use at the following indications. The patient has neurological disorders, e.g. muscular weakness in the lower extremities, especially the foot, resulting in ankle instability. A typical example is drop foot. The disorder may be caused by neurological disorders, tumors, infection, radiation treatment, and trauma etc. Contraindications are e.g. severe spasticity, ankle edema and diabetes with ulcers.

As is mentioned previously, an important object of the ankle-foot orthosis of the invention is to achieve a more natural and dynamic gait. A normal gait pattern has been aimed at and was used as a basis in developing the orthosis. The orthosis also assists in coordinating the foot movement by keeping the structures of the foot in a functional position.

A gait cycle analysis using the orthosis of the invention is shown in Figure 4. The lower curve is for a

prior art orthosis, the intermediate curve for an orthosis according to the present invention (medium soft version), and the top curve for a normal healthy person. The force is measured by a foot plate on the floor, that is the vertical force exerted by a person walking. At the heel strike the body weight is transferred through the front part of the orthosis. This is the left-hand peak of the curves. The elasticity of the flexible portion 6 of the foot plate allows a gradual dorsal flexion of the foot in dependence of the body weight, the motion velocity and the position of the lower leg relative to the ground. From the supporting phase to the toe-off phase the orthosis protects the foot from inversion and eversion by bridging the ankle joint. The toe-off phase is represented by the right-hand peak of the curves. As is seen from Figure 4, the patient using the prior art orthosis cannot obtain the necessary force during toe-off, but the patient using the orthosis of the present invention obtains an increased force. Of course, this increased forced does not act on the weak foot but on the leg where the orthosis is carried. In fact, the springing action of the foot plate resembling a recoil effect will assist the patient to move forward and enables the patient to take longer steps. The flexibility of the foot plate will also promote a more natural gait.

Thus, it will be seen that the ankle-foot orthosis according to the invention has various advantages. The orthosis is of an extremely low weight, approximately 110 grams for the medium size and softness, which is very important for patients having weaknesses in the leg muscles. The orthosis is very thin enabling use of normal shoes and even boots. The elasticity of the foot plate promotes a more natural gait reducing the stresses on the front part of the foot. The orthosis stabilizes the ankle joint to prevent a distortion tendency. The orthosis may be individually adjusted by cutting or grinding the edges of the foot plate or other edges of the fibre glass reinforced plastic.

Furthermore, the orthosis is primarily in contact with the front part of the lower leg avoiding contact with sensitive areas such as the Achilles tendon, the heel and malleoli which often are subject to swelling and are sensi-

tive to touch. It is a fact that the width of the ankle and the size of the heel bone varies over a wide range as seen for a normal healthy population. Thus, it is an advantage that the orthosis of the invention does not cover these portions of the foot-ankle joint but extends over the lateral ankle only. The orthosis is simple to put on and take off; only two straps are securing the orthosis against the leg. The orthosis is put on by first placing the foot plate in the shoe. Thereafter the shoe is put on with the orthosis in place. If pressure points and sharp edges are experienced, these may be eliminated by applying a soft padding on the inside of the orthosis.

While the present invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications may occur to those skilled in the art without departing from the true spirit and scope of the invention as defined by the appended claims.

CLAIMS

1. An ankle-foot orthosis comprising:

a frame of thin flexible material extending over the front of the lower leg, anterior of the lateral ankle and beneath the sole of the foot;

a supporting portion of rigid material extending over a narrow part of the front of the lower leg, anterior of the lateral ankle and beneath a part of the sole of the foot; and

a fastening means for fastening the orthosis to the leg.

2. An ankle-foot orthosis according to claim 1, wherein the supporting portion comprises a substantially inflexible reinforcement element and a tough flexible element.

3. An ankle-foot orthosis according to claim 2, wherein said reinforcement element extends over a narrow part of the front of the lower leg, anterior of the lateral ankle and beneath a narrow part of the sole of the foot and said flexible element extends over a substantial part of the sole of the foot.

4. An ankle-foot orthosis according to claim 2 or 3, wherein said reinforcement element is made of carbon fibre reinforced plastic resin and said flexible element is made of aramid fibre reinforced plastic resin.

5. An ankle-foot orthosis according to any one of the previous claims, wherein the frame is made of thin flexible fibre-glass reinforced plastic resin material.

6. An ankle-foot orthosis according to any one of the previous claims, wherein the fibre-glass reinforced plastic consists of a number of layers of yarn fabric impregnated with an epoxy matrix.

7. An ankle-foot orthosis according to any one of the previous claims, wherein each fibre-glass reinforced layer is ≥ 0.2 mm thick.

8. An ankle-foot orthosis according to claim 6 or 7, comprising two or three fibre-glass reinforced layers.

9. An ankle-foot orthosis according to any one of the previous claims, wherein the carbon fibre reinforced plastic consists of a number of layers of single-direction carbon fibre fabric impregnated with an epoxy matrix.

10. An ankle-foot orthosis according to claim 9, wherein each carbon fibre reinforced layer is arranged at an angle to other layers.

11. An ankle-foot orthosis according to any one of claims 1 to 8, wherein the carbon fibre reinforced plastic consists of a number of layers of twill-woven carbon fibre fabric impregnated with an epoxy matrix.

12. An ankle-foot orthosis according to claim 9, 10 or 11, wherein each carbon fibre reinforced layer is ≥ 0.3 mm thick.

13. An ankle-foot orthosis according to any one of the previous claims, comprising one to four carbon fibre reinforced layers.

14. An ankle-foot orthosis according to any one of the previous claims, wherein the foot plate comprises three fibre-glass reinforced layers, two aramid fibre reinforced layers, and two carbon fibre reinforced layers.

15. An ankle-foot orthosis according to any one of claims 1 to 13, wherein the foot plate comprises three fibre-glass reinforced layers, three aramid fibre reinforced layers, and two carbon fibre reinforced layers.

16. An ankle-foot orthosis according to any one of claims 1 to 13, wherein the foot plate comprises four fibre-glass reinforced layers, four aramid fibre reinforced layers, and three carbon fibre reinforced layers.

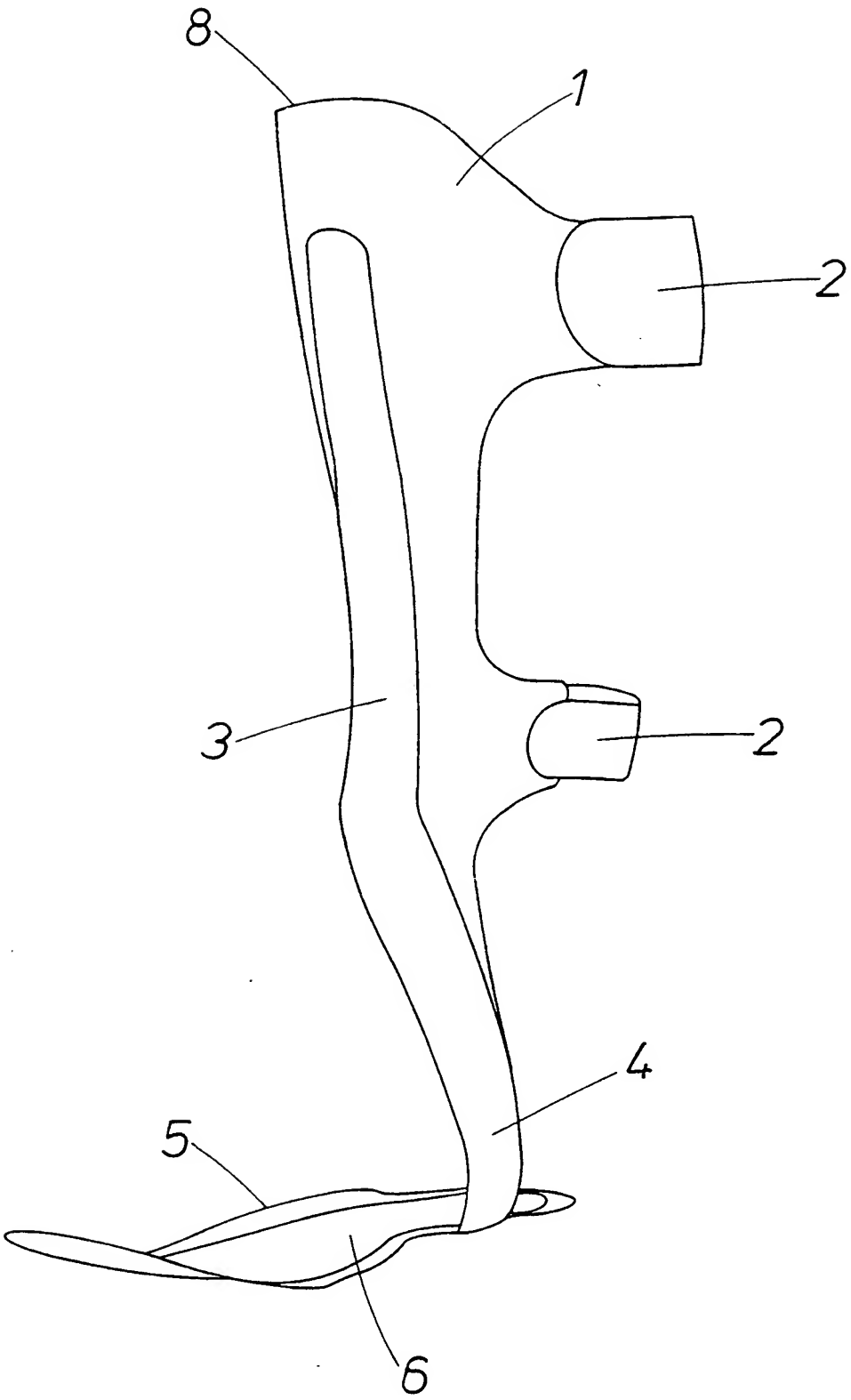

Fig.1

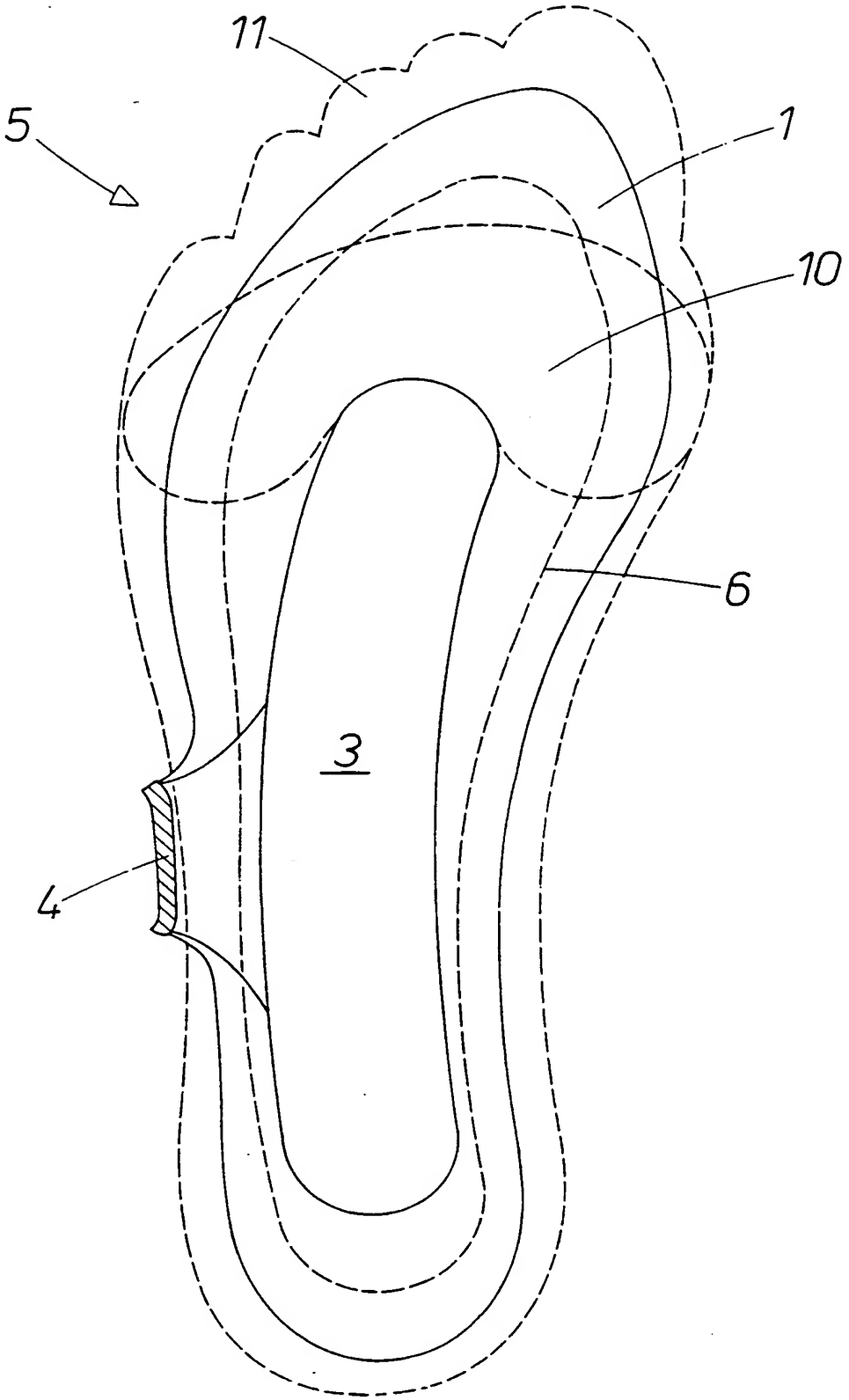

Fig.2

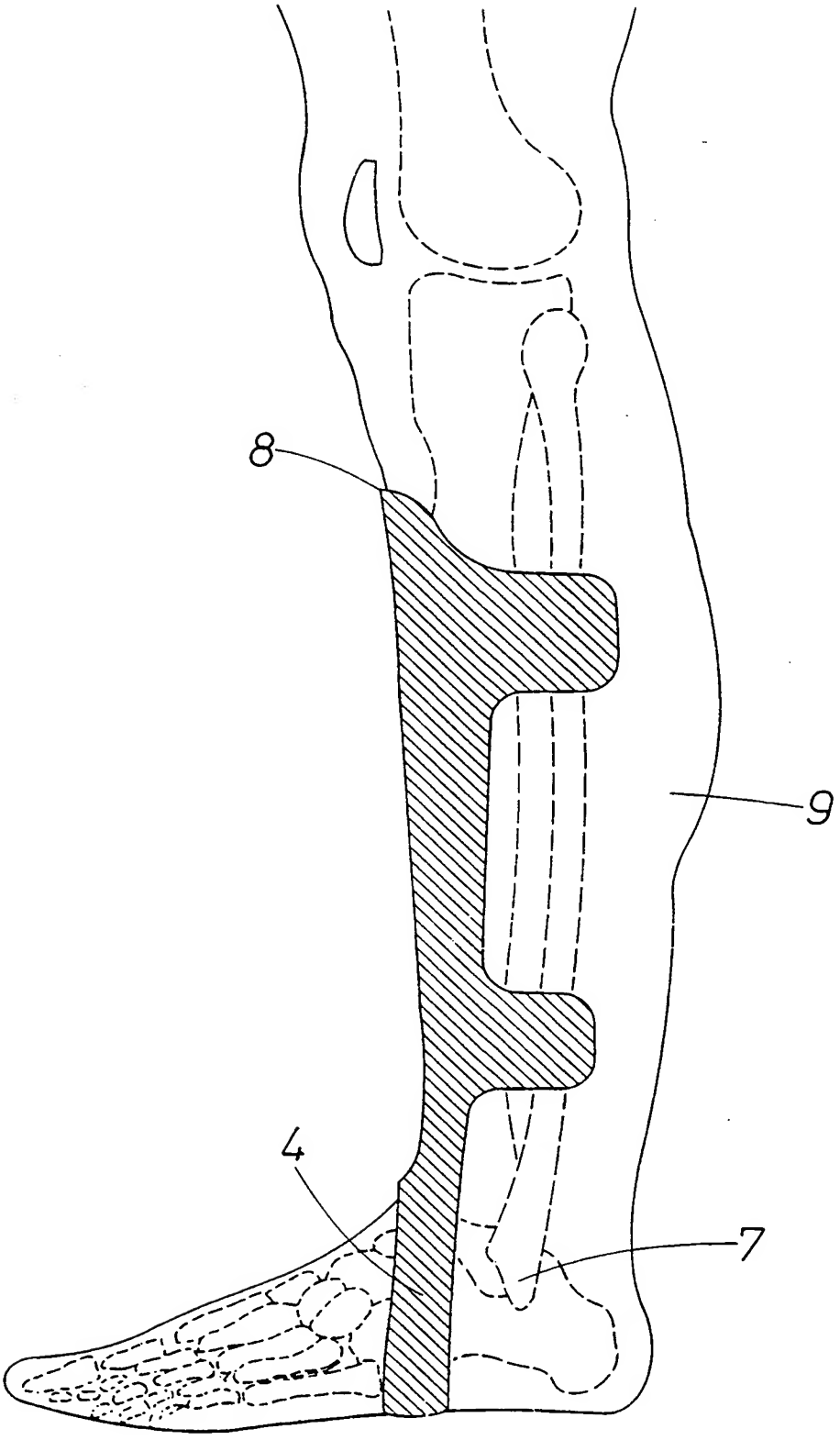

Fig.3

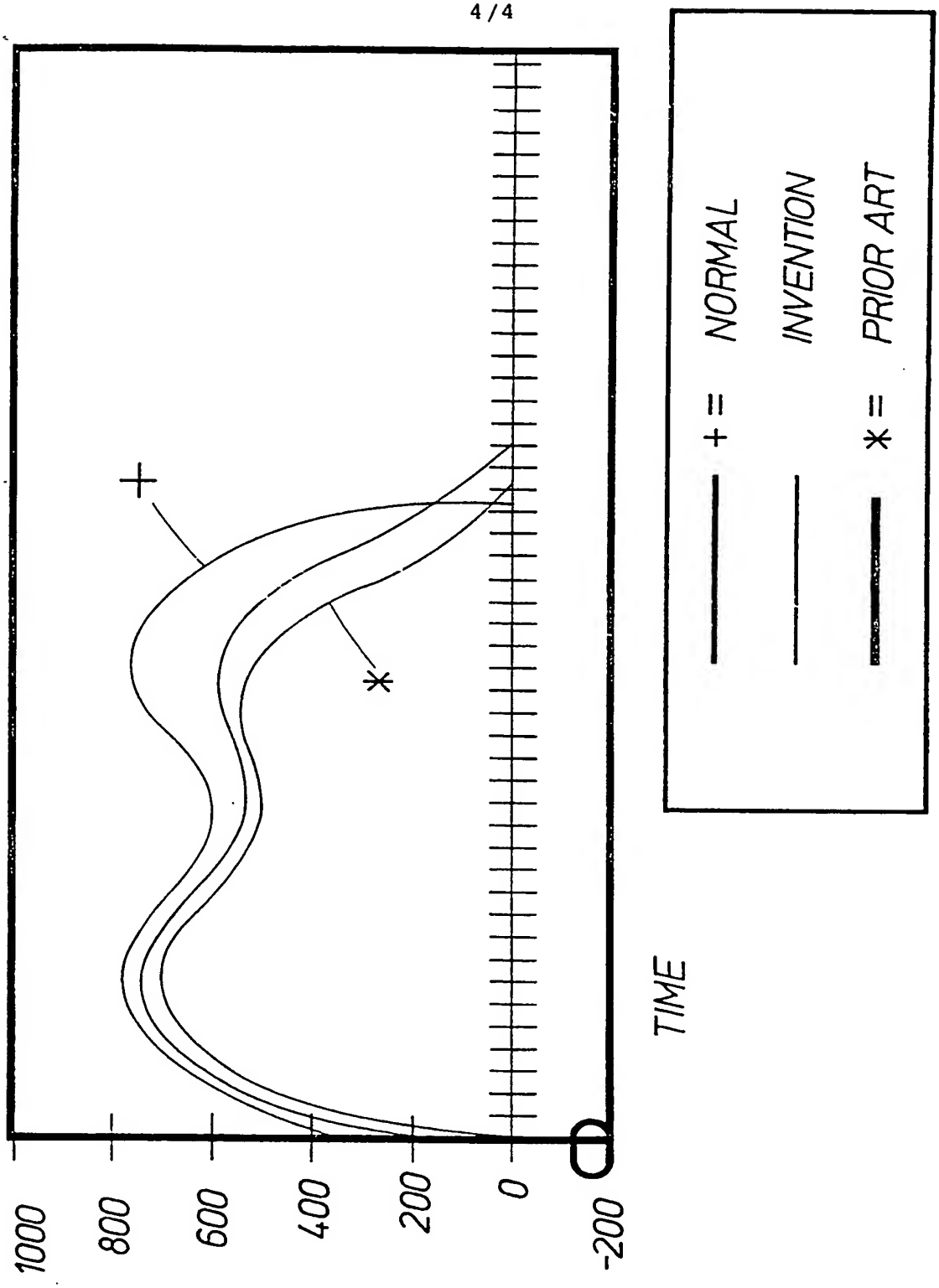

Fig.4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 97/01253

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/37, A61F 13/04
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 9531950 A1 (STIG WILLNER ET AL.), 30 November 1995 (30.11.95), figures 1-2, claims 1-9	1-16
Y	US 4862900 A (W.J. HEFELE), 5 Sept 1989 (05.09.89), column 3, line 4 - line 60, figures 1-2	1-16
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A	WO 9400083 A1 (ANDREWS, BRIAN), 6 January 1994 (06.01.94), page 3, line 7 - line 25, figures 2-3	1

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Date of the actual completion of the international search	Date of mailing of the international search report
17 December 1997	22.12.1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/97

International application No.
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